

**ON-LINE PHARMACIES AND THE SALE OF CANADIAN  
PRESCRIPTION MEDICATIONS TO THE UNITED STATES**

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## TABLE OF CONTENTS

	<b>Page</b>
INTRODUCTION .....	1
THE LEGALITY OF TRANSBORDER PRESCRIPTION AND SALE OF PRESCRIPTION MEDICATIONS .....	3
A. Canada's Position.....	3
1. Compliance With the Pharmacists' Code of Ethics.....	3
2. Risks and Concerns Associated With Prescribing Prescription Medications Over the Internet .....	4
3. The Canadian Pharmacists Association's Position on the Distance Prescription and Sale of Medications.....	5
B. The American Position.....	5
1. The <i>Medicare Prescription Drug, Improvement, and             Modernization Act of 2003</i> and State Laws .....	5
2. U.S. Regulatory Agencies' Efforts to Ensure Compliance with the Law.....	7
3. The Citizens' Movement to Change the Laws.....	8
THE CANADA/U.S. PRICE DIFFERENTIAL AND PRICE CONTROL.....	9
A. The Canadian Monitoring and Price Control System .....	9
1. Patented Medications .....	10
2. Non-patented Medications and the Degree of Competition .....	12
3. Public Drug Insurance Plans (Pharmicare Programs).....	13
B. The American System at the Centre of the Debate .....	14
ECONOMIC ISSUES.....	15
A. American Public Health Financing.....	15
B. Financial Stakes for Pharmaceutical Companies .....	16
1. The Segmentation of Canadian and U.S. Markets.....	16
2. Imports, Free Trade and Pharmaceutical Companies .....	17
3. Advertising.....	17
C. The U.S. Government's Response: Medicare.....	18
CONCLUSION.....	19



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## ON-LINE PHARMACIES AND THE SALE OF CANADIAN PRESCRIPTION MEDICATIONS TO THE UNITED STATES

### INTRODUCTION

Some Americans find it difficult to obtain affordable prescription medications, a situation that has given rise in Canada to an industry that creates both wealth and jobs: the transborder trade in such medications. Although the exact scale of the industry is not known, well-informed observers agree that it is growing rapidly.<sup>(1)</sup>

Some have estimated that sales of prescription medications to the United States reached the billion-dollar mark in 2002, double the figure for the previous year. According to the Food and Drug Administration (FDA),<sup>(2)</sup> more than two million parcels containing prescription medications for personal use enter the United States each year. The *Wall Street Journal*<sup>(3)</sup> states that approximately 70 Canadian pharmacies (including 40 in Manitoba) shipped Canadian prescription medications worth over US\$500 million (approximately C\$675 million) to the United States in 2002. Furthermore, the Canadian International Pharmacy Association puts annual sales by the industry even higher, at US\$650 million (approximately C\$865 million).

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- (1) Transborder trade in prescription medications has generated hundreds of jobs in Canada (some sources estimate 2,500 jobs, but the figure is difficult to confirm), particularly in Manitoba, where laws on filling U.S. prescriptions are less restrictive. It is estimated that 10-20% of Manitoba's 1,500 pharmacists now work for an on-line pharmacy. The province's premier, Gary Doer, supports a State of Minnesota project whereby the state would sell medications to its 50,000 civil servants through Internet pharmacies based in Manitoba.
  - (2) The FDA is the U.S. federal agency responsible for the protection of public health, including the safety of pharmaceuticals (<http://www.fda.gov/opacom/hpview.html>).
  - (3) Joel Baglole, "Getting the Gray Out," *Wall Street Journal*, New York, 13 February 2003.

The dazzling growth in sales of Canadian prescription medications to U.S. citizens is due to three main factors:

- Canadian prices are well below U.S. prices for the same prescription medications;
- the exchange rate between the Canadian and U.S. dollar still gives Americans an advantage;
- the geographic proximity of Canadian pharmacies involved in transborder sales makes it convenient for Americans to purchase these products.

Trade in prescription medications, particularly over the Internet, has given rise to heated debate in the United States. On the one hand, the regulatory health authorities are opposed to it for legal reasons and are concerned about the health of U.S. consumers and of the American medication distribution system. On the other hand, a growing number of American citizens and politicians see Canadian prescription medications as an economical alternative to the prohibitive costs of pharmaceuticals in the United States.

The U.S. debate made the front pages in Canada when, on 27 October 2003, Health Canada sent a letter to the main Canadian agencies responsible for regulating the pharmaceuticals industry and to provincial ministries of Health, expressing a number of concerns about the risks inherent in Internet pharmaceutical sales:

Cross-border sales of prescription drugs via the growing practice of internet pharmacy also raise the potential for drug shortages domestically. Health Canada regards this as a very serious matter due to the inherent risk to Canadians' health.<sup>(4)</sup>

In January 2003, GlaxoSmithKline Inc. (GSK) advised on-line pharmacies and its distributors that it did not permit its products to be exported. GSK maintained that the export of Canadian medications to the United States represented a serious threat to the Canadian health system, because it was exhausting inventories of medications intended for Canadians; it was also jeopardizing the safety of American patients by giving them access to Canadian medications outside of the American regulatory system.

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(4) Health Canada, Health Products and Food Branch, Letter to provincial pharmacy associations, medical associations, pharmacy regulatory authorities, medical regulatory authorities, the National Association of Pharmacy Regulatory Authorities, Canadian Pharmacists Association, and provincial/territorial ministries of Health, 27 October 2003 (<http://www.hc-sc.gc.ca/english/pdf/protection/letter.pdf>).

In March 2003, the Canadian Competition Bureau supported GSK's decision to stop supplying on-line pharmacies that were exporting products intended for the Canadian market to the United States. According to the Bureau, such transborder sales violated American law, and GSK was therefore justified in terminating these exports while continuing to supply the Canadian market. On 4 August 2003, GSK announced that it would no longer sell its products to wholesalers. Eight days later, Pfizer, the largest pharmaceuticals firm in the world – even larger than GSK – in turn announced that it would no longer supply Canadian pharmacies that sold its products to American consumers.

This report provides an overview of the controversy and issues related to the transborder trade in prescription medications, in particular via the Internet, by setting out the facts and the arguments of the main stakeholders.

## **THE LEGALITY OF TRANSBORDER PRESCRIPTION AND SALE OF PRESCRIPTION MEDICATIONS**

### **A. Canada's Position**

In Canada, pharmacies and pharmacists are governed by the provinces and territories. At present, prescribing drugs through the Internet (prescribing, not selling) and transmitting prescriptions over the Internet are prohibited. In November 2001, the National Association of Pharmacy Regulatory Authorities (NAPRA)<sup>(5)</sup> approved a *modus operandi* for pharmacists who offer their services on the Internet, to ensure that exemplary professional practices are followed. Several provinces and territories have just reviewed their policy, or are in the process of developing a policy, on the delivery of pharmaceutical services via the Internet, in particular with respect to the sale of prescription medications abroad.

#### **1. Compliance With the Pharmacists' Code of Ethics**

For those Canadian authorities and agencies that monitor the exercise of the pharmacist's profession in Canada, the sale of prescription medications – whether in Canada, in the United States or elsewhere in the world – is above all an issue of compliance with the code of

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(5) NAPRA (<http://www.napra.org/docs/0/95/158/186.asp>) is an association of colleges of pharmacists (also known as pharmaceutical associations and pharmaceutical societies) from the provinces and territories except Ontario, Quebec and Nunavut.

ethics rather than a legal matter. The distance selling of prescription medications or the transborder sale of such medications, whether via the Internet or other means, is a public safety concern. Compliance with the pharmacists' code of ethics is of primary importance to Canadian public safety. Failure to comply with the code may expose the public to certain risks arising from the inappropriate use of pharmaceuticals. Many associations of Canadian health care professionals – including the Canadian Pharmacists Association, NAPRA, the Ontario Pharmacists' Association, the College of Physicians and Surgeons of Ontario, and the Ordre des pharmaciens du Québec – have expressed serious concerns about the lack of personal consultation with the client and the health risks involved in the use of on-line pharmacies.

## **2. Risks and Concerns Associated With Prescribing Prescription Medications Over the Internet**

The Canadian Pharmacists Association (CPA)<sup>(6)</sup> has expressed the following concerns about a number of Canadian Web sites that sell prescription medications to the United States and other countries.

- Some Internet sites operate illegally and services are not provided by accredited pharmacies. These bypass the comprehensive safety system of premarket medication approval, prescription requirements, patient assessment by a health care provider, and pharmacy standards of practice. People who purchase medications from the operators of such sites risk experiencing adverse effects from inappropriately prescribed medications, interactions among different medications, contaminated or counterfeit medications, etc.
- Purchasing medications over the Internet bypasses the opportunity for face-to-face consultation with a pharmacist, physician or other health care provider.
- The medication distribution, storage, labelling, handling and packaging processes may be compromised.
- Because it is illegal to transmit a prescription over the Internet, prescriptions are often faxed. They could be faxed to multiple on-line pharmacies, thereby increasing the potential for diversion, illicit use and trafficking in medications.
- Internet pharmacies may not have complete patient profiles, thus limiting their ability to monitor for risks associated with allergies and drug interactions.
- Some Internet pharmacies require their patients to sign a waiver or release that relieves the pharmacist of any ethical or legal obligation as a condition of providing service. Such a practice may undermine accountability, which is a key element of the pharmacist-patient relationship.

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(6) The CPA (<http://www.pharmacists.ca/index.cfm>) is a national volunteer organization that represents Canadian pharmacists.

- Some Canadian physicians forward prescriptions received from another country to on-line pharmacies, without speaking to the patient or the foreign prescriber. Physicians are remunerated for this service by the patient, the on-line pharmacy or an intermediary. Medical regulatory agencies have informed their members that the practice of co-signing prescriptions without having examined the patient may be considered a breach of professional ethics.
- The privacy and confidentiality of patients' personal and financial information may be compromised on some sites.
- The current situation might aggravate the shortage of pharmacists across Canada, as some pharmacists spend their time filling prescriptions for U.S. and other non-Canadian citizens.
- Some provincial regulations require that pharmacists not contravene laws in the jurisdiction where the patient resides. Many U.S. states have legislation that requires a pharmacist or the pharmacy to be licensed in the state in order to dispense drugs to its citizens.

### **3. The Canadian Pharmacists Association's Position on the Distance Prescription and Sale of Medications**

The Canadian Pharmacists Association opposes the prescription and sale of prescription medications when the patient, the pharmacist and the attending physician do not have a close professional relationship, because the practice under such conditions may jeopardize the patient's health. Public health is the guiding principle underlying the CPA's position on this matter. The CPA is also opposed to the prescription and sale of prescription medications abroad where such a practice contravenes the laws of the jurisdiction where the patient resides.

#### **B. The American Position**

##### **1. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and State Laws**

On 8 December 2003, President George W. Bush signed the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*,<sup>(7)</sup> which contains new provisions concerning the importing of prescription medications into the United States. Generally speaking, pharmacists and wholesalers may import such medications under certain conditions, but individuals may not. Section 804 of the new Act amends Chapter VIII of the *Federal Food, Drug and Cosmetic Act*, which governed such trade, and maintains the prohibition on individuals from directly importing Canadian or foreign prescription medications, including via the Internet. The U.S. regulatory authorities, and in particular the FDA, say that this

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(7) White House, "President Signs Medicare Legislation," press release, 8 December 2003 (<http://www.whitehouse.gov/news/releases/2003/12/20031208-2.html>).



prohibition is necessary to protect the health of Americans. The FDA and the National Association of Boards of Pharmacy (NABP)<sup>(8)</sup> put forward essentially the same arguments as the Canadian Pharmacists Association.

Section 804 of the new Act clearly states that the new import conditions ought not to constitute a risk to the health and safety of Americans and that they should lead to a significant lowering of the price of prescription medications for the consumer. More specifically, the import conditions require that:

1. the imported prescription medications comply with FDA requirements, including those relating to safety and effectiveness;
2. the importer (pharmacist or wholesaler) meet FDA requirements by sending the Secretary of Health all relevant documentation concerning:
  - the composition of the medication;
  - the dosage form;
  - the date it was shipped from Canada;
  - the quantity imported;
  - the price paid by the importer;
  - documentation to the effect that the medication may be sold in the United States;
  - the identification certificate number of the product delivered by the manufacturer, and documentation demonstrating that it complies with manufacturing standards and specifications;
  - the name, address and telephone number of the importer (including the professional licence number);
  - documentation demonstrating that each batch was statistically sampled and tested for authenticity and degradation;
3. the exporter supply relevant documentation concerning the source of the medication and the quantity received from the manufacturer for each batch;
4. the exporter register with the Health Secretary;

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(8) The NABP (<http://www.nabp.net/>) is a professional association that represents colleges of pharmacists in all 50 U.S. states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, New Zealand, eight Canadian provinces and three Australian states. The NABP claims to be independent and impartial, and it assists its members in developing, implementing and enforcing uniform pharmacy standards for the purpose of protecting public health.

5. imports of a medication be immediately suspended upon discovery of counterfeiting or violation of any requirement of the Act, until an investigation is completed and the Health Secretary determines that the public is adequately protected and that the Act is being complied with.

The Health Secretary may authorize an individual – on an exceptional basis, case by case, and under certain very limited conditions – to import prescription medications from abroad. Such medications, however, must be imported for the exclusive use of an individual (maximum supply of 90 days) and are not to be resold by a licensed pharmacist. This provision does not, therefore, involve authorizing large-scale importing of foreign versions of medications approved in the United States, even through a pharmacist or wholesaler.<sup>(9)</sup>

At the moment, 43 U.S. states require that pharmacies outside out of the state register with the board of pharmacy in the state to which they are shipping their pharmaceuticals. U.S. pharmacies that fail to do so are liable to legal action. According to an investigation conducted by the NABP in August 2002, the laws in nine U.S. states are sufficiently broad to allow for the registration of foreign pharmacies.<sup>(10)</sup> Thus far, however, the federal law has prevented the registration of foreign pharmacies with state boards of pharmacy. This situation is symptomatic of the confusion surrounding current debate in the United States: some states can in theory grant legal recognition to entities that openly contravene a federal law. It remains to be seen how the states will harmonize their own laws with the new provisions of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*.

## **2. U.S. Regulatory Agencies' Efforts to Ensure Compliance with the Law**

In reality, the FDA and the state boards of pharmacy do not really have the means to enforce their laws. Their numerous appeals to Canadian authorities, Canadian pharmacies and American citizens have proved ineffectual. In a report that describes the serious concerns about U.S. citizens' imports of prescription medications from Canada, the NABP relates that the Oregon Board of Pharmacy wrote to the British Columbia College of Pharmacists asking that it pressure the province's pharmacists to comply with American laws. The College's response was

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(9) Large quantities of prescription medications are currently imported and re-imported perfectly legally by pharmaceutical companies with offices in the United States. American and international pharmaceutical companies have plants around the world. According to the International Trade Commission, imports of pharmaceuticals to the United States by pharmaceutical companies totalled US\$14.7 billion in 2001.

(10) NABP, "Position Paper on the Importation of Foreign Drugs," March 2003.

to remind the U.S. authorities that it was their responsibility to monitor imports of prescription medications from abroad and that the College's responsibility was limited to ensuring that all pharmacies under its authority comply with provincial laws and the professional code of ethics.

The FDA's efforts to intercept parcels containing prescription medications from abroad are also hampered by regulations requiring that the Administration notify purchasers of foreign prescription drugs that their parcels have been seized. The recipient must then give the FDA reasons why the parcel in question should be allowed to enter U.S. territory. If the reasons are not justified, or if no reply is received, the FDA must return the parcel to the shipper, which in this case would be the on-line pharmacy. This procedure requires enormous human and financial resources, which the FDA clearly does not have.

### **3. The Citizens' Movement to Change the Laws**

While U.S. regulatory agencies are attempting to enforce the law and requesting more resources to do so, some high-level politicians are organizing bus trips so that their constituents can purchase their medications in Canada and Mexico. A number of insurance companies and social benefit program authorities recommend or even require that their clients or employees purchase Canadian prescription medications because they are less expensive.

Several American states, including Minnesota and Illinois, encourage the purchase of prescription medications in Canada. The Governor of Illinois, Rod Blagojevic, even circulated a petition on the Internet to ask the Congress to amend the *Food, Drug and Cosmetic Act* to allow Americans to purchase prescription medications in Canada.<sup>(11)</sup>

Furthermore, this initiative has broad popular support, as demonstrated by a poll conducted by the Kaiser Family Foundation: 68% of Americans surveyed wanted the current law amended to allow the purchase of prescription medications in Canada.<sup>(12)</sup>

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(11) See the State of Illinois Web site (<http://www.illinois.gov/>).

(12) Kaiser Family Foundation, "Support for Prescription Drug Importation," *Kaiser Health Poll Report*, September 2003 (<http://headlines.kff.org/healthpollreport/feature1/media/feature.pdf>).

## THE CANADA/U.S. PRICE DIFFERENTIAL AND PRICE CONTROL

The significant gap between the price of prescription medications in Canada and the United States is the main reason for the development of transborder trade in these products.<sup>(13)</sup>

The price of medications in either country is initially determined by the following factors:

- demand by consumers and doctors' prescription practices
- manufacturers' business strategies, including promotional campaigns with doctors and pharmacies
- the degree of market competition
- pressure by private insurance companies.

Thereafter, the gap between prices in the two countries begins to open up. Prices of prescription medications sold in Canada are monitored directly by federal authorities and indirectly by provincial and territorial public drug insurance plans. The strength of the American dollar compared to Canada's currency is another factor that encourages U.S. consumers to purchase their prescription medications in Canada.

### A. The Canadian Monitoring and Price Control System

In Canada, medication prices are subject to a system of controls and constraints that are more or less direct, depending on whether or not the medications in question are patented. *Patented* or *proprietary* medications are those for which a patent has been issued. *Unpatented* medications are those for which a patent has never been requested or for which the patent has expired, and generic copies.

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(13) The gap varies over time, from product to product, and by point of sale in the United States. However, the U.S. price may be double the Canadian price for certain products.

## 1. Patented Medications

In Canada, the Patented Medicine Prices Review Board (PMPRB)<sup>(14)</sup> is responsible for regulating the prices that manufacturers of patented medications can charge for products intended for human or veterinary use that are distributed in Canada by prescription or non-prescription sale, and for ensuring that these prices are not excessive.

When, as a result of a public hearing, the Board determines that the price of a medication is excessive, it may require the patentee to reduce the price and take whatever action is required to reimburse the excess amounts charged.

The PMPRB regulates the “factory gate” price that the manufacturer charges to wholesalers, hospitals or pharmacies. It also regulates the prices of patented medications sold or distributed under voluntary licences. It does not regulate the prices of non-patented medications, including generic products sold under compulsory licences, and has no jurisdiction over prices charged by wholesalers or retailers, or over pharmacists’ fees.

The *Patented Medicines Regulations, 1994*<sup>(15)</sup> require that patentees submit reports on introductory prices for their medications and on their sales of new patented medications within 60 days of initial sale. They must then submit detailed quarterly reports on prices and sales for each patented medication, for as long as the patent is in force. The PMPRB reviews all price data for each patented medication sold in Canada to ensure that these prices comply with the guidelines published in its *Compendium of Guidelines, Policies and Procedures*.

The guidelines take into account the factors set out in section 85 of the *Patent Act* for determining whether prices are excessive. They were developed in consultation with a variety of stakeholders, including the provincial and territorial ministers of Health, consumer associations and pharmaceutical industry representatives. In general, they ensure that:

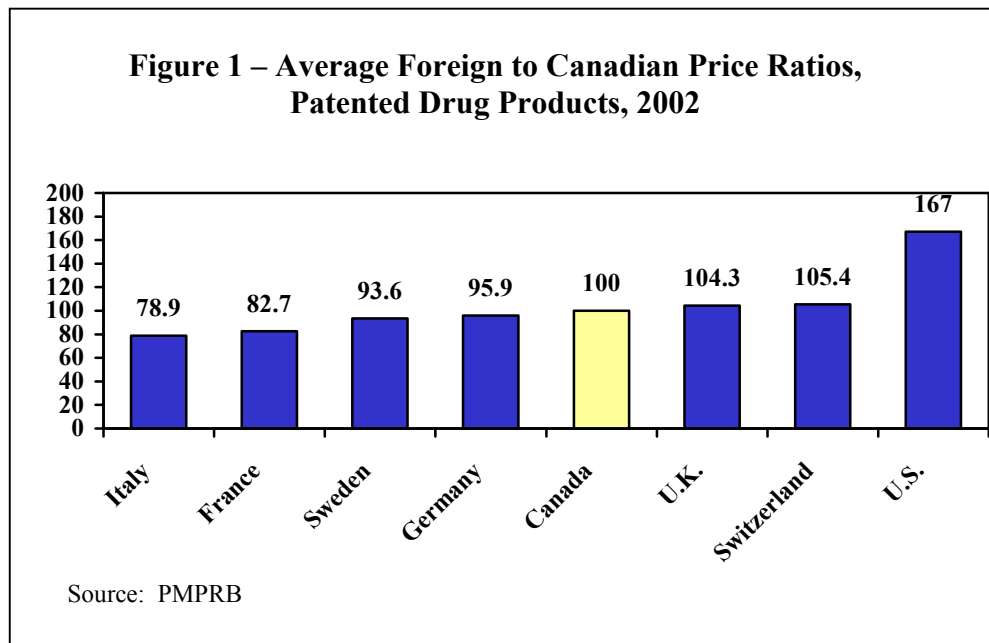
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(14) The PMPRB is an independent, quasi-judicial body created by Parliament in 1987 under the *Patent Act*. It protects consumer interests and contributes to the Canadian health system by ensuring that prices charged by manufacturers of patented medications in Canada are not excessive. The PMPRB reports to Parliament through the Minister of Health. Its annual report, which covers the calendar year, relates its main activities, analyzes the price of patented medications, and reports on price trends of all pharmaceutical products. It also reports on spending on research and development by pharmaceuticals patentees.

(15) *Patented Medicines Regulations, 1994*, SOR/94-688  
(<http://laws.justice.gc.ca/en/P-4/SOR-94-688/160396.html>).

- the prices of most new patented medications are limited to ensure that the cost of therapy using those medications is no higher than the cost of therapy already used in Canada to treat the same problem;
- the prices of patented medications that involve a discovery or make a significant improvement are no higher than the median price in the seven industrialized countries named in the *Regulations*: Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States;
- the rates of price increases for existing patented medications are no higher than the consumer price index;
- the price of a patented medication in Canada is never higher than the highest price for the same medication in the seven industrialized countries named in the *Regulations*.

According to the PMPRB, in 2002, Canadian prices were 1% higher than the international median prices of the seven countries used for comparative purposes; they were lower than in the United Kingdom, Switzerland and the United States, but higher than in Italy, France, Sweden and Germany.<sup>(16)</sup> As in previous years, prices in the United States were much higher than in Europe or Canada.



(16) PMPRB, *Annual Report 2002*, p. 8 (<http://pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf>).

## 2. Non-patented Medications and the Degree of Competition

No agency has a specific mandate to directly monitor or regulate the prices of non-patented medications sold in Canada. Prices are unregulated and there is no central reporting mechanism like the system for patented medications. Information about the prices of these medications is therefore hard to come by; existing data are disparate and scattered among the various buyers of medications in Canada (e.g., provincial drug insurance plans or insurance companies).

In Canada, the two factors that most affect the price of non-patented medications are keen competition in the marketplace, and drug insurance programs.

Some non-patented medications are distributed on an exclusive basis, meaning that they are sold by a single manufacturer, thereby avoiding the competitive process. Medications in this category, which constitute a relatively small market, have no generic equivalents in Canada. These medications are distributed on a single-source basis in Canada, but are not necessarily sold on that basis in other countries. A recent study showed that the factory gate prices in Canada for non-patented, single-source medications are on average much higher (28%) than the median prices in six European countries (France, Germany, Italy, Sweden, Switzerland and the United Kingdom). However, these prices were generally lower in Canada than in the United States (Americans paid an average of 96% more than Canadians for the products selected for this comparison).<sup>(17)</sup>

When a patent expires, the manufacturer loses the exclusive right to sell its “brand-name” medication. Other manufacturers are then allowed to compete, usually in the form of generic products marketed after the patent has expired. At this point, competition is primarily at the price level. Promotions are aimed at pharmacists rather than doctors.

A generic medication is a bioequivalent version of a brand-name medication: it contains the same active chemical ingredient(s) and has the same strength, dosage form, and route of administration. It is often produced by several manufacturers, but may also be made by a single manufacturer. The manufacturer of a brand-name medication may also produce a generic version, which is then called “ultra-generic,” in order to compete with manufacturers of generic medications.

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(17) PMPRB, *Top Selling Non-Patented Single Source Drug Products: International Price Comparison, 1998-1999*, study conducted for the Federal/Provincial/Territorial Working Group on Drug Prices, no date.

The price of generic medication is established in relation to the price of the brand-name version. It is also influenced by the price of the ultra-generic medications on the market. Generally speaking, generic medication is sold at a lower price than the brand-name equivalent. The keener the competition, the lower the price of the generic version. An analysis of data from 1990 to 1995 showed that the price of a generic medication generally approximates 77.6, 65.3 or 62.6% of the price of the corresponding brand-name product, depending on whether one, two or three generic versions are on the market.<sup>(18)</sup>

Manufacturers of brand-name and generic medications can also use differential price strategies for different packaging formats. Generic medications now have a greater share of the prescription medication market than 10 years ago. This increase is partly attributable to the policies of most public drug insurance plans (pharmacare programs), which encourage the use of generic products where possible.

### **3. Public Drug Insurance Plans (Pharmacare Programs)**

The price of medications is strictly controlled by each province's mechanism for registering medications whose price is guaranteed under the public drug insurance plan.<sup>(19)</sup> In Quebec, for example, each manufacturer must submit a "guaranteed selling price" for each format of any medication that it wishes to register on the list established under section 60 of the *Act Respecting Prescription Drug Insurance*.<sup>(20)</sup> The situation is similar in the other provinces.

The guaranteed selling price is the highest price that a buyer can pay for a medication. It can be lowered by any reduction agreed to by the manufacturer in the form of a discount, rebate or incentive, and any free samples offered to the buyer by the manufacturer. The guaranteed selling price must include, in addition to the amount that constitutes the price, any amount required for marketing, service, guarantee, commissions, transportation or delivery, as well as any other amount added for any other reason, except for charges that may be levied by the seller because of the buyer's failure to comply with payment conditions in the contract of sale. The

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(18) Health Canada, *Drug costs in Canada, Brief submitted to the House of Commons Standing Committee on Industry for the review of the Patent Act Amendment Act, 1992*, March 1997, p. 17 (<http://dsp-psd.pwgsc.gc.ca/Collection/H42-2-1997E.pdf>).

(19) The guaranteed selling price applies to both patented and non-patented medications.

(20) *Act Respecting Prescription Drug Insurance* [Loi sur l'assurance médicaments], R.S.Q., c. A-29.01, s. III, "List of Medications" ([http://www.ramq.gouv.qc.ca/fr/professionnels/listmed/pdf/novembre/annexe\\_1.pdf](http://www.ramq.gouv.qc.ca/fr/professionnels/listmed/pdf/novembre/annexe_1.pdf)).



manufacturer agrees to respect that guaranteed selling price in dealings with wholesalers and pharmacists. The guaranteed selling price is established as follows:

- it must be submitted for each format of the medication (the number of formats being limited to two), and it must take into account any price agreed to for multiples of the format(s);
- the price may differ for sales to pharmacists versus sales to wholesalers, but the difference may not exceed 9%;<sup>(21)</sup>
- the price shall remain in force for the period that the list of medications is valid;
- the price shall not exceed any selling price agreed to by the manufacturer for the same medication under other provincial drug insurance plans.

This last point demonstrates that the provinces and the territories have more or less become unofficial oligopsonies<sup>(22)</sup> in the Canadian marketplace, which gives them considerable buying power and a form of price control.

## **B. The American System at the Centre of the Debate**

In the United States, the price of medications is not controlled in any way, except perhaps as a result of pressure from insurance companies and Health Maintenance Organizations; accordingly, it obeys market forces. The FDA, which is responsible for certifying medications and protecting public health, is responsible for the safety of pharmaceuticals, but does not regulate their price.

There is general agreement in the United States that this lack of price controls is part of the reason for the high price of medications compared to those in Canada and Europe. Another influential line of argument in the United States is that the high prices that Americans pay for medications constitute an indirect subsidy to consumers in other countries, where pharmaceutical companies may sell at a loss in order to comply with national regulations, and that U.S. consumers are basically supporting the cost of pharmaceutical research.<sup>(23)</sup>

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(21) Conversely, the wholesaler, in establishing a selling price, agrees not to ask more than 9% above the manufacturer's guaranteed selling price, taking into account the format of the medication being sold.

(22) An oligopsony is a market in which there are only a few buyers. The price in an oligopsony market is somewhere between the competitive price and the monopsony, or buyer's monopoly, price.

(23) Edward H. Crane and Roger Pilon, "Conservative Drug Split: Reimportation is right and good," *National Review Online*, 29 July 2003 (<http://www.nationalreview.com/comment/comment-crane-pilon072903.asp>).

The crisis in public financing and the slow economic recovery, which has left millions of Americans without adequate medical coverage, has given rise to heated debate at all levels of U.S. society. What steps must be taken to help consumers who are having trouble paying for the medication they need to remain healthy? Some advocate opening up the American market completely to imports of medications from other countries (free trade); some seek other solutions, because they fear the impact of free trade on the American pharmaceutical industry; others again are advocating better coverage for prescription medications under public programs such as Medicare.<sup>(24)</sup> In all the scenarios, the economic stakes are high for both the United States and Canada.

## ECONOMIC ISSUES

### A. American Public Health Financing

Although Americans obtain health care coverage most often under an employer's group insurance plan, 45% of health care expenses in the United States are covered by the states and the federal government. The federal government spends 22% of its budget on Medicare, a universal health care plan for the elderly and disabled,<sup>(25)</sup> and Medicaid, a health care program for low-income individuals.<sup>(26)</sup> The U.S. states spend approximately 30% of their budgets on health, and this percentage is rising.<sup>(27)</sup>

Spending under the Medicaid program – which is approximately 21% of state spending – increased by 13.2% (to \$285 billion, of which \$111 billion is paid by the states) in the 2002 fiscal year. As everywhere else in the world, health care costs have been rising steadily, largely as a result of the aging population and rising medication prices. Given the significant

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(24) The *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, which was signed on 8 December 2003, established a partial drug insurance plan in the United States. See “The U.S. Government's Response: Medicare,” below.

(25) See the Medicare Web site (<http://www.medicare.gov/default.asp>).

(26) The Medicaid program provides 47 million of the most disadvantaged U.S. citizens with medical coverage. Although the federal government established the program's overall principles and basic standards, the states set the eligibility criteria. Participation in the program therefore depends on an individual's state of residency.

(27) National Association of State Budget Officers (NASBO), *2001 State Expenditures Report*, Washington, D.C., Summer 2002 (<http://www.nasbo.org/Publications/PDFs/nasbo2001exrep.pdf>); see also NASBO, *Medicaid and Other State Healthcare Issues: Current Trends*, June 2003 (<http://www.nasbo.org/Publications/Medicaid/medicaidfeature2003.pdf>).

budgetary problems at various levels of government in the United States,<sup>(28)</sup> it is not surprising that the states and local governments, which are forbidden by law to post deficits, are looking for any ways they can cut their spending – for example, by importing less expensive Canadian medications. Several state governments are attempting to make them available to their own employees, whose health coverage they pay for in part.

## **B. Financial Stakes for Pharmaceutical Companies**

The basic issue with respect to the price of medications is the need to strike a balance between the demand for affordable medications and the financial imperatives of the pharmaceutical companies, for whom high prices are an incentive to continue research and the development of new products. In short, lower prices provide better access to medications, but reduce profitability and discourage research.

### **1. The Segmentation of Canadian and U.S. Markets**

For the major pharmaceutical companies, the U.S. market is key, because most of their sales and profits come from that market. During the year that ended in October 2002, the Canadian market accounted for 2.6%, and the American market for 53.4%, of the \$638.8 billion (in factory gate prices) in sales of medication for human use on the major world markets.<sup>(29)</sup> The U.S. market is by far the largest in the world, accounting for twice the total combined sales in Canada, France, Italy, Germany and the United Kingdom.

A number of American observers have concluded that pharmaceutical companies put up with price control mechanisms in Canada and Europe because they can achieve a reasonable profit margin in the U.S. market, where there are no price controls. This is known as market segmentation and price discrimination. Furthermore, pharmaceutical companies have agreed to Canadian and European prices (which are linked) in exchange for patents offering them longer protection.

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(28) On this topic, see P. Le Goff, *Taxation in the Canadian Provinces and American States: Heading for Convergence?* PRB 03-12E, Parliamentary Research Branch, Library of Parliament, Ottawa, 1 October 2003 (<http://lpintrabp.parl.gc.ca/lopimages2/prbpubs/bp1000/prb0312-e.asp>).

(29) IMS Health, *Retail Drug Monitor*, October 2002 ([www.imshealth.com](http://www.imshealth.com)). The amounts include direct and indirect pharmaceutical channel purchases (pharmacies, hospitals and mail order where applicable) from pharmaceutical wholesalers and manufacturers in 13 key international markets. Figures include data on prescription and over-the-counter medications at manufacturer prices. The 13 countries in question – Germany, Argentina, Australia, Brazil, Canada, Spain, the United States, France, Italy, Japan, Mexico, New Zealand and the United Kingdom – account for more than two-thirds of the world market.

## **2. Imports, Free Trade and Pharmaceutical Companies**

Pharmaceutical companies are vigorously opposed to U.S. imports of Canadian medications. As indicated above, they have taken steps to stop supplying on-line pharmacies that export to the United States, and they have been pressuring Washington to strengthen enforcement of the U.S. laws that prohibit the practice.

Indeed, importing foreign medications amounts to importing the price controls practised by countries such as Canada. Eliminating non-tariff barriers and allowing American consumers to purchase medications at prices below domestic market levels constitutes a direct threat to pharmaceutical companies' profitability. The companies maintain that opening up the American market completely to foreign medications at current prices could mean losses of approximately \$US600 billion over a period of 10 years.

That being the case, pharmaceutical companies will resist any move by the U.S. government to adopt a free trade policy, because such a policy would trigger a collapse in the price structure and distribution system for prescription medications. In the short and medium terms, a free trade environment could lead pharmaceutical companies to reconsider their research and development spending in the United States, and they might threaten to pull out of the local market in countries that persist in imposing price controls. It is very unlikely that governments in Canada and Europe will want to deprive their people of essential medications in order to maintain existing price controls. It is more likely that a free trade environment would push prices up in Canada and Europe to even out the profit margins in the industrialized countries where pharmaceutical companies make most of their sales. From this standpoint, Health Canada's concerns about the long-term indirect impacts of on-line trade in medications are justified.

## **3. Advertising**

Although pharmaceutical companies claim that completely opening up the U.S. market to Canadian medications would affect their ability to invest in research and development, that sector is not their largest area of expenditure. According to the Governor of the State of Illinois, annual reports for 1999 show that spending on marketing, public relations and administration by the 10 largest U.S. pharmaceutical companies was three times as high as their research and development spending. Since the FDA eased the restrictions on television advertising of prescription medications in 1997, spending on advertisements of all types aimed at

the general public increased from \$791 million to \$2.5 billion (in 2000). Spending on television advertising made a remarkable leap, from \$220 million in 1996 to \$1.6 billion in 2000.<sup>(30)</sup>

According to the consulting firm Scott-Levin,<sup>(31)</sup> as cited in an article published in *USA Today* in May 2001,<sup>(32)</sup> the number of sales representatives in the U.S. pharmaceutical industry almost doubled between 1996 and 2000, from 41,800 to 83,000. The industry also spent \$5.3 billion in 2000 to advertise in specialist medical journals and to visit doctors' offices to promote products. In that same year, it also spent almost \$2 billion to sponsor over 314,000 events attended by doctors.

These costs are passed on to American consumers of prescription medications and contribute to the price difference between Canada and the United States. Importing Canadian medications would thus threaten not only pharmaceutical research but also, downstream, the advertising and sale of prescription medications.

### **C. The U.S. Government's Response: Medicare**

Medicare, the U.S. public health insurance plan for less well-off elderly and disabled people, has often been criticized for not including prescription drug insurance – which is why so many elderly Americans buy their medications in Canada.

However, in the middle of the controversy over imports of Canadian medications, and in response to heavy demand by pressure groups representing the elderly, President Bush, as noted above, recently signed the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, which will make it possible for the 40 million Medicare recipients to have part of their prescription medication costs reimbursed. In the spring of 2004, they will receive a card giving them discounts of between 10 and 25% on the purchase price of prescription drugs.

Elderly people earning less than \$12,124 per year (\$16,363 for married couples) will be entitled to an additional discount of up to \$600 per year. Beginning in 2006, all Medicare claimants will have access to discounts on prescription medications. By paying an average monthly premium of \$35, participants in the plan will see their drug bills decrease by half. Those less well-off will not have to pay a monthly premium. The new Act provides for

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(30) State of Illinois, "Get the Facts," *The Fight for Affordable Prescription Drugs*, 2003 (<http://www.affordabledrugs.il.gov/factsheet.cfm>).

(31) See the Scott-Levin Web site ([http://www.verispan.com/about/scott\\_levin.asp](http://www.verispan.com/about/scott_levin.asp)).

(32) Julie Appleby, "Sales pitch: Drug firms use perks to push pills," *USA Today*, 16 May 2001 (<http://www.usatoday.com/news/health/2001-05-16-perks-usat.htm>).

reimbursement of 95% of expenses over \$3,600 per year. The annual deductible amount will be a maximum of \$50, and each prescription will require co-payment of a maximum fee of \$3. According to the figures provided by the U.S. government, elderly people who spend \$800 per month for their prescription drugs will receive a 61% discount, or \$5,868 per year. Those who spend up to \$400 per month will save 50%, or approximately \$2,404 per year.<sup>(33)</sup>

Management of this new component of Medicare will be entrusted to the private companies that already purchase health care for their clients from care providers. Medicare claimants who have a prescription drug insurance plan from a former employer may also receive discounts on their prescription medications through a subsidy made available to the employer.

The initiative has been welcomed by pharmacies and U.S. pharmaceutical companies. Under this new program, the U.S. government will inject an additional \$400 billion in the retail medication market over the next 10 years. However, international experience has shown that cost overruns are frequent and that forecasts are risky.

## CONCLUSION

The on-line pharmacy phenomenon focuses attention on a number of issues that are typical of the early years of this century: protectionism and the use of massive subsidies by the United States at a time when markets are being globalized (e.g., steel, agriculture); the problems faced by governments in regulating transborder trade on the Internet; and the pressure exerted on public financing by the skyrocketing health costs associated with the consumption of medications.

As for the future of on-line pharmacies, it is hard to evaluate the long-term impact of the Bush Administration's new program on the price differential between Canada and the United States. Consequently, it is difficult to forecast sales by on-line pharmacies. It is nevertheless clear that in the short term (until 2006), the program's clientele is too restricted to significantly disrupt the current activities of on-line pharmacies. It remains to be seen how Canadian authorities will react to Canadian health care professionals who use on-line pharmacies and in doing so violate U.S. laws. It is also difficult to anticipate the attitude of major political players in the United States who are currently lobbying to allow purchases of Canadian prescription medications, once the new program takes full effect in 2006.

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(33) United States Department of Health and Human Services, *Secretary Thompson Applauds Final Passage of Medicare Bill*, press release, 25 November 2003 (<http://www.hhs.gov/news/press/2003pres/20031125.html>).